UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

RANDALL GOLDMAN	§	
	§	
Plaintiff,	§	
	§	
v.	§	Civil Action 4:20-cv-00463
	§	
XAVIER BECERRA,[1]	§	
Secretary of the United States	§	
Department of Health and	§	
Human Services,	§	
	§	
Defendant.	§	

DEFENDANT'S RESPONSE TO PLAINTIFF'S OBJECTIONS TO THE MAGISTRATE'S REPORT AND RECOMMENDATION

Defendant, Xavier Becerra, Secretary of the U.S. Department of Health and Human Services (the "Secretary") respectfully requests that the District Court adopt the Magistrate Judge's Memorandum and Recommendation (Doc. 55) and dismiss this case due to Plaintiff's lack of standing.

I. Introduction

In April 2014, Medicare beneficiary Randall Goldman, was diagnosed with a deadly form of brain cancer called glioblastoma multiforme ("GBM"). AR 12. In 2016, he began using a tumor treatment field therapy ("TTFT") device manufactured by Novocure known as Optune. AR 12. Although Medicare Part B covers certain types of durable medical equipment ("DME"), Medicare does not cover everything, including items or services which are not considered "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Prior to September 2019, the relevant

[1] Pursuant to Fed. R. Civ. Proc. 25(d), Xavier Becerra, should be substituted for Alex M. Azar as Defendant in this action.

Local Coverage Decision ("LCD") stated that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." AR 43.[2] The four ALJ decisions on appeal denied Plaintiff's Medicare claims for TTFT from October 27, 2017 through February 27, 2019 based on that LCD. Although the ALJ decisions denied Plaintiff's TTFT claims, the ALJ's waived his liability for payment. Accordingly, no matter the outcome of this case, the Secretary will neither pay any money to Plaintiff nor require Plaintiff to pay out-of-pocket. Novocure, the supplier of the TTFT treatment, is precluded from collecting payment from Plaintiff because it did not demonstrate it provided him with an Advanced Beneficiary Notice (ABN).

The Memorandum and Recommendation issued on June 25, 2021, by Magistrate Judge Christina A. Bryan recommended the court dismiss the case because Plaintiff is not financially liable for payment of denied TTFT claims and thus lacks Article III standing. Mem. at 6. The Magistrate Judge concluded that: 1) Goldman has not suffered a concrete injury, and 2) Goldman's allegation of future harm is too speculative to constitute an injury in fact as required for Article III standing. The Magistrate Judge's Memorandum and Recommendation is fully consistent with the majority of caselaw, including the Seventh Circuit's recent opinion in *Prosser v. Becerra*, 2 F.4th 708 (7th Cir. 2021); which rejected every argument raised in Plaintiff's Objection.

[2] The determination to include an item or service in the non-coverage category in an LCD means that no beneficiary will receive such coverage. *See, e.g.*, *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 767 n. 4 (5th Cir.2011) (stating that "[a] carrier may automatically deny claims when a 'clear policy serves as a basis for denial' for that type of claim" and categorizing an LCD as setting forth such a policy); *Vertos Med., Inc. v. Novitas Sols., Inc.*, No. CIV.A. H-12-3224, 2012 WL 5943542, at *2 (S.D. Tex. Nov. 27, 2012)(citing *Wolcott*).

II. Argument

A. District Court's Review of the Memorandum and Recommendation

A party is entitled to "a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1)(C); Fed. R. Civ. P. 72(b)(3); *Longmire v. Guste*, 921 F.2d 620, 624 (5th Cir. 1991). Un-objected to portions are reviewed for clear error. 28 U.S.C. 636(b)(1). General conclusory arguments and nonspecific objections do not warrant de novo review and are reviewed for clear error. *See Edmond v. Collins,* 8 F.3d 290, 293 (5th Cir.1993); *Battle v. U.S. Parole Comm'n*, 834 F.2d 419, 421 (5th Cir. 1987) (per curiam)(citations omitted)("The objections must be clear enough to enable the district court to discern those issues that are dispositive and contentious."). Moreover, a plaintiff who fails to present specific factual objections to a Magistrate Judge's report and recommendation has not raised a factual objection for the court to address. *Edmond v. Collins*, 8 F.3d at293 (No factual objection is raised when a petitioner merely reurges arguments contained in the original petition). In conducting a de novo review, the Court is not "required to reiterate the findings and conclusions of the Magistrate Judge." *Koetting v. Thompson,* 995 F.2d 37, 40 (5th Cir. 1993).

B. The Magistrate Judge correctly determined that a violation of a statutory right, without any accompanying actual or imminent injury, does not constitute an injury in fact sufficient to confer Article III standing.

The U.S. Constitution limits federal-court jurisdiction to actual cases or controversies. *Raines v. Byrd*, 521 U.S. 811, 818 (1997); U.S. Const. Art. III, § 1. Standing to sue is a doctrine derived from this limitation on judicial power. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The "irreducible constitutional minimum" of standing consists of three elements: the plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged

conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Id*. (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). Plaintiff bears the burden of establishing these elements and must clearly allege facts demonstrating each element at the pleading stage. *Id*. The following table reflects holdings in similar identical TTFT cases. The Seventh Circuit (*Prosser*) and six district courts (*Thumann, Wilmoth, Oxenberg, Prosser, Komatsu, Pehoviack*) have dismissed similar cases for lack of standing. The *Banks* district court granted the Secretary's motion for summary judgment and rejected plaintiff's collateral estoppel argument. Considering standing in the first instance on appeal, the Eleventh Circuit rejected plaintiff's statutory standing argument, but remanded to the district court for additional jurisdictional factfinding. Meanwhile, only one district court found standing (*Townsend*). As discussed further below, the Court should follow the persuasive reasoning in the nearly unanimous decisions rejecting Plaintiff's arguments and dismissing for lack of standing.

Case	**District Court Ruling**	**Appellate Status**
Prosser v. Azar, No. 20-cv-194, 2020 WL 6266040 (E.D. Wis. Oct. 21, 2020), *aff'd*, *Prosser v. Becerra*, 2 F.4th 708 (7th Cir. June 25, 2021) ("*Prosser*")	Dismissed for lack of standing	Affirmed
Banks v. Azar, No. 20-cv-565, Dkt. No. 52 (N.D. Ala. Mar. 30, 2021), *vacated and remanded on other grounds*, --- F. App'x ---, 2021 WL 3138562 (11th Cir. July 26, 2021) ("*Banks*")	Granted the Secretary's motion for summary judgment regarding collateral estoppel	Vacated and remanded for a determination on standing
Thumann v. Cochran, No. 20-cv-125, 2021 WL 1222142 (S.D. Ohio Mar. 31, 2021) ("*Thumann*")	Dismissed for lack of standing	Appeal dismissed, No. 21-3502 (6th Cir. Aug. 2, 2021)
Wilmoth v. Azar, No. 20-cv-120, 2021 WL 681118 (N.D. Miss. Feb. 22, 2021) ("*Wilmoth*")	Dismissed for lack of standing	Appeal dismissed, No. 21-60351 (5th Cir. August 5, 2021)

Oxenberg v. Azar, No. 20-cv-738 (E.D. Pa. Feb. 9, 2021)	Dismissed for lack of standing	Pending
Komatsu v. Azar, No. 20-cv-280, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020) ("*Komatsu*")	Dismissed for lack of standing	Appeal dismissed, No. 20-56001, 2020 WL 7865597 (9th Cir. Oct. 2, 2020)
Pehoviack v. Azar, No. 20-cv-661, 2020 WL 4810961 (C.D. Cal. July 22, 2020) ("*Pehoviack*")	Dismissed for lack of standing	Appeal dismissed, No. 20-55841 (9th Cir. Dec. 10, 2020)
Townsend v. Cochran, No. 20-cv-1210, 2021 WL 1165142 (S.D.N.Y. Mar. 25, 2021) ("*Townsend*")	Denied motion to dismiss for lack of standing	No appeal

Like most of the cases above, Plaintiff lacks Article III standing because he cannot meet his burden of showing that he suffered an injury in fact. The record before the Court reflects that the denial of Plaintiff's Medicare claims did not interfere with his treatment or result in any personal financial liability. In response, Plaintiff counters that he suffered an injury in fact because the denial of his Medicare claims cost him his "substantive statutory right" to have Medicare pay his claims, and put him on notice that Medicare might not cover future claims, such that he faces a substantial risk of personal financial liability in the event of a future claim denial. Neither of these arguments has merit.

Plaintiff has not identified a statutory violation, because he has no "entitlement" to Medicare coverage. Plaintiff asserts that the Medicare laws "entitle" him to coverage for their TTFT claims. The Seventh Circuit recently rejected Plaintiff's position, writing:

> Congress, in enacting Medicare, did not endow an individual with a substantive right to payment by Medicare each and every time they submit a claim. After all—and as the facts here show—Medicare payments most often go to the supplier or provider, not the recipient of care.

Prosser, 2 F.4th at 714; *See*, Mem. at 7 (Medicare's refusal to pay the claims did not cause Goldman to suffer an individual, concrete injury. Goldman has a statutory right to seek Medicare benefits, to receive all reasonable and necessary treatment at minimal cost, and to appeal denial of coverage.").

Plaintiff fails to cite any statute guaranteeing coverage for their TTFT claims because none exists. To the contrary, DME coverage cannot be provided unless the device is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(1)(A). The Supreme Court has foreclosed arguments that interfere with the Secretary's broad discretion to determine Medicare coverage, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). The Fifth Circuit has recognized that, "to include an item or service in the non-coverage category in an LCD means that no beneficiary will receive such coverage." *See, e.g.*, *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 767 n. 4 (5th Cir.2011) (stating that "[a] carrier may automatically deny claims when a 'clear policy serves as a basis for denial' for that type of claim" and categorizing an LCD as setting forth such a policy); *Vertos Med., Inc. v. Novitas Sols., Inc.*, No. CIV.A. H-12-3224, 2012 WL 5943542, at *2 (S.D. Tex. Nov. 27, 2012)(citing *Wolcott*).

Even if Plaintiff had established his entitlement to Medicare coverage (which he has not), he has not shown that his alleged statutory injury is a concrete harm that has "long been seen as injurious" under the common law. *See Spokeo*, 136 S.Ct. at 1549 ("whether an alleged intangible harm has a close relationship to a harm that has traditionally been regarded as providing a basis

for a lawsuit in English or American courts"); *Thorne*, 980 F.3d at 890 (evaluating whether there is a "historical analogue that could remedy the alleged harm").

The Supreme Court recently explained the plain meaning of the standing doctrine. In *TransUnion LLC v. Ramirez*, 141 S.Ct. 2190 (2021), the Supreme Court wrote:

> To have Article III standing to sue in federal court, plaintiffs must demonstrate, among other things, that they suffered a concrete harm. No concrete harm, no standing. Central to assessing concreteness is whether the asserted harm has a "close relationship" to a harm traditionally recognized as providing a basis for a lawsuit in American courts—such as physical harm, monetary harm, or various intangible harms . . .

Id. at 2200. For standing purposes, therefore, an important difference exists between (i) a plaintiff's statutory cause of action to sue a defendant over the defendant's violation of federal law, and (ii) a plaintiff's suffering concrete harm because of the defendant's violation of federal law. Congress may enact legal prohibitions and obligations. And Congress may create causes of action for plaintiffs to sue defendants who violate those legal prohibitions or obligations. But under Article III, an injury in law is not an injury in fact. Only those plaintiffs who have been concretely harmed by a defendant's statutory violation may sue that defendant in federal court. Plaintiff's first argument fails because under *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016), an alleged statutory violation is insufficient to confer Article III standing. Plaintiff's second argument fails because there has been a change in circumstances from the time of the Medicare claim denials on appeal—the revision of the LCD for his treatment—that renders his risk of personal financial liability in the event of a future claim denial completely speculative. Accordingly, Plaintiff cannot meet his burden of showing an injury in fact, so the Court should dismiss this case with prejudice for lack of Article III standing.

C. The Magistrate Judge correctly determined that Plaintiff's allegation of future harm is too speculative to constitute an injury in fact as required for Article III standing

Second, Plaintiff asserts that, if the decisions on appeal stand, he will lose his "mulligan," which protects a beneficiary without knowledge that their claim could be denied from out-of-pocket liability. Pl.'s Obj at 7. The Magistrate concluded that, "whether Goldman could be held financially responsible for future TTFT depends on a chain of decisions made by different decision-makers in the multi-step appeals process; thus, while his alleged future harms are conceivable, they fall short of a "factual showing of perceptible harm" or imminent harm that would constitute an injury in fact sufficient to confer Article III standing and federal court jurisdiction." Mem at 8, citing, *See Wilmoth*, 2021 WL 681118, at *4 (quoting *Lujan*, 544 U.S. at 566) (finding argument of future harm based on analogous facts too speculative to establish standing; plaintiff's future harm of financial liability depended on a chain of decisions made by different actors in the appeals process).

There is also no impending risk that Plaintiff's "mulligan" will be lost in a future claim appeal. That could only happen in a hypothetical scenario in which a series of unlikely events happen to coincide. Plaintiff's claims were denied under the 2015 LCD, which categorically denied TTFT coverage, while his recent TTFT claims have been approved under the current LCD, which provides coverage. Plaintiff offers no reason to suspect that a future claim would be denied under the current LCD. But even if one were, Plaintiff's "mulligan" would only be lost if an administrative decision improbably found that a claim denial under the 2015 LCD was a "comparable situation[]" to a denial under the current LCD. 42 U.S.C. § 1395pp(b). Even then, Plaintiff would not lose his "mulligan" if that decision were reversed on appeal. And even if Plaintiff's mulligan were lost, he would have no out-of-pocket costs unless Novocure changed

course and insisted that Plaintiff sign an ABN and written agreement accepting personal responsibility in the event of a claim denial.

In sum, Plaintiff has neither suffered a past intangible injury nor shown an impending future injury. Even if he had, however, he fails to identify a "close historical or common-law analogue for their asserted injury" and thus fails to show a concrete harm under Article III. *TransUnion LLC v. Ramirez*, 141 S.Ct. 2190, 2204 (2021). Plaintiff's purported entitlement to Medicare payment and loss of "mulligan" are merely creatures of statute, and "under Article III, an injury in law is not an injury in fact." *Id*. at 2205.

In *Prosser*, the court held that Prosser did not have standing to bring her claim for Medicare coverage of Optune because she faced no financial liability for the denied claim and any future risk of denial is far too speculative to establish standing. *Id*. The Seventh Circuit noted that:

> Far too many steps lay between the instance coverage denial and any future liability. Novocure would need to require Prosser to sign an advanced beneficiary notice, acknowledging her own financial liability should Medicare deny coverage for the therapy. The company has not done so, and there is nothing in the record to suggest it might do so in ***the future.***

The Magistrate Judge's conclusion is consistent with the Seventh Circuit's well-reasoned opinion and should be adopted by the District Court.

D. The Holt Decision Does Not Support Plaintiff's Standing Argument

Plaintiff attached a 2019 ALJ decision regarding another beneficiary to his Objection in an effort to bolster his erroneous argument that "knowledge" may be established *either* by an ABN or by a "recent claim denial for the same item or service." Obj. at 8. Although knowledge may be based on recent denials for many types of Medicare claims, this argument misstates the law applicable to durable medical equipment, like TTFT.

The Decision by ALJ Holt (Holt Decision - Pl.'s Ex. A) found the beneficiary financially responsible not because of a prior ALJ decision, but rather because of a "letter written by the [b]eneficiary appealing Medicare's denial of his physician's authorization request for coverage of [TTFT] using the Optune system." Pl.'s Ex. A at 13. In other words, the denial of pre-approval and the beneficiary's claim both arose under an LCD that categorically denied coverage. The Holt Decision is not binding upon Plaintiff and is not a final decision by the Secretary; rather, it is non-precedential and has been vacated. *See* (CMS Ex. 1). The Holt Decision, like the decisions presently on appeal, was issued under the 2015 LCD, which categorically denied TTFT coverage. The Holt Decision is simply an ALJ case that reached a legal conclusion at odds with statute and caselaw.

Under the statute, if Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). A supplier of the medical treatment or device can only shift the risk of non-coverage and bill the beneficiary only when the beneficiary has received sufficient advance notice of the risk of noncoverage to permit "an informed consumer decision about receiving items or services for which they may have to pay out-of-pocket." *Int'l Rehab. Scis., Inc. v. Sebelius*, 688 F.3d 994, 998 (9th Cir. 2012). A supplier typically satisfies this requirement by providing the beneficiary with an advance written notice (called an "Advance Beneficiary Notice" or "ABN") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b); *see Int'l Rehab. Scis., Inc.,* 688 F.3d. at 997-98 (explaining that a valid ABN is required "for the supplier to shift liability to the beneficiary"); *Almy v. Sebelius*, 679 F.3d 297, 311 n. 4 (4th Cir. 2012) (same); *Cal. Clinical Lab. Ass'n v. Secretary of HHS*, 104 F. Supp. 3d 66, 72 (D.D.C. 2015)

(same); *see also* Medicare Claims Processing Manual (Manual) ch. 30, §§ 50.2.1 (If notice of liability is not given, "providers may not shift financial liability to beneficiaries . . . if Medicare denies the claim"), 50.2.2 (a supplier "who fails to comply with the ABN instructions risks financial liability and/or sanctions."), 50.4.1 (deeming suppliers to be "notifiers," which must issue ABNs), 50.4.2 ("Notifiers are required to give an ABN to a [] Medicare beneficiary . . . before providing him/her with a Medicare covered item or service that may not be covered").[3]

Additional requirements are imposed on DME suppliers, who must not only provide such advance notice but also obtain a written agreement in advance from the beneficiary agreeing to pay in the event Medicare coverage is denied:

> (4) Limitation on Patient Liability
>
> If a supplier of medical equipment and supplies . . .
>
> (A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);
>
> (B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or
>
> (C) furnishes an item or service to a beneficiary for which payment is denied under section 1395y(a)(1) of this title;
>
> any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

42 U.S.C. § 1395m(j)(4). *See Prosser v. Becerra*, 2 F.4th 708, 711 (7th Cir. 2021) ("Medical device suppliers—as opposed to healthcare providers in general—bear an additional burden should they wish to shift the risk that coverage may be denied: they must obtain a written

[3] The Medicare Claims Processing Manual is available at https://www.cms.gov/ Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf.

agreement by the patient that she will individually bear the cost of coverage denial."); Manual, ch. 30 § 30.1 (noting that for DME suppliers, beneficiary knowledge "must be evidenced by a signed written notice and agreement to pay personally in case of a denial.").[4]

Although section 1395m(j)(4) refers to claims that are "not on an assigned basis," a similar provision limits beneficiary liability for assigned claims. As a non-participating supplier, Novocure may elect to accept assignment on a case-by-case basis. *See* 42 C.F.R. § 400.202 (defining a "nonparticipating supplier" as "a supplier that does not have an agreement with CMS to participate in Part B of Medicare in effect on the date of the service"). An assignment agreement transfers to the supplier the beneficiary's right to bill and receive Medicare payment, but the supplier agrees "not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of" section 1395y(a). 42 U.S.C. § 1395u(b)(3)(B)(ii). In sum, the Medicare laws limit beneficiary liability for both unassigned and assigned claims. *See* Manual, Ch. 30 § 150 ("For both assigned and unassigned claims, for which the supplier knew or should have known of the likelihood that payment would be denied (that is, the supplier is held to be liable) and for which the beneficiary did not know, the beneficiary has no financial responsibility and the refund provisions of the Act apply in virtually all cases.").

Absent an ABN and written agreement, there is no basis for Plaintiff to be held liable for a denied TTFT claim. Meanwhile, there is no evidence that Plaintiff has been asked to sign an

[4] Plaintiff misrepresents the Manual by selecting a snippet from a *full-page* flowchart. Pl.'s Obj at 8. In fact, that flowchart gives the contractor discretion to determine whether the beneficiary's knowledge may be established due to notice of a recent claim denial for the same item or service, and, if not, instructs the contractor to determine if the supplier is liable. Manual, ch. 30 § 30. Plaintiff also mistakenly cites the general beneficiary knowledge requirement, rather than the knowledge requirement applicable to DME suppliers. Pl.'s Obj. at 9.(citing § 30.1).

ABN or written agreement in connection with TTFT. There is also no evidence that Novocure intends to require Plaintiff to sign an ABN or written agreement in the future.

Plaintiff started receiving TTFT in 2016, and prior to the four decisions on appeal, he had received a denial of pre-authorization for TTFT (*exactly like the beneficiary in Holt Decision)* and he had also received receive 10 prior denials of TTFT; which were administratively final. AR 243-244; 290. If the Holt Decision was correct, Plaintiff clearly had knowledge TTFT was not covered under the prior LCD and he would have already lost his "mulligan" to 2014 LCD long before this case arose. However, the four ALJ decisions at issue in this case found that Plaintiff was not financially liable because he has not signed an ABN, which is the law. AR 116 ("There was no valid Advance Beneficiary Notice of Non-Coverage, so the Beneficiary/Appellant shall not be liable for the non-covered supplies."), 4594, 9094.

Plaintiff has used TTFT for five years, but he has not presented any evidence that *he:* 1) has ever been found financially liable for any denied TTFT claims; 2) has been asked to sign an ABN or agreement to pay for denied claims; 3) has been denied TTFT treatment; 4) has been denied Medicare coverage of TTFT based on the 2019 LCD; or even has any other denied claims on appeal.

Even if an ABN was not necessary to shift liability to the Plaintiff, it is purely speculative that an ALJ would find the four denials in this case under the 2015 LCD to be instructive as to Plaintiff's knowledge that a claim under the 2019 LCD might be denied. Accordingly, the Holt Decision, which is non-precedential and has been vacated, does not support Plaintiff's standing and should be disregarded.

III. Conclusion

For the reasons set forth in the Defendant's pleadings, the Court should adopt the Magistrate's Report and Recommendations and dismiss this case.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the *Defendant's Response to Plaintiff's Objections* was sent via ECF on August 13, 2021, to all counsel of record:

/s/ Jimmy Rodriguez
Assistant United States Attorney